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DIETARY SUPPLEMENTS AND PREGNANT WOMEN

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Good Afternoon. I appreciate having an opportunity to comment on a very important health issue - the use of dietary supplements by pregnant women.

The Dietary Supplement Health and Education Act or DSHEA allows manufacturers to make claims related to the effect of their products on the structure and function of the body, but no claims about diseased states. Interestingly, since pregnancy and menopause are considered normal conditions, claims for dietary supplement claims are allowed. I want to focus my remarks on pregnant and nursing women.

There are many difficult questions on this issue. One is "Why are drugs for treating disease held to a more stringent standard than botanicals or dietary supplements used by healthy people?" I am not advocating that we should have lower standards for drugs but that products used by healthy people, particularly pregnant and nursing women, need to have standards which are based on sound scientific information.

DSHEA was crafted to allow truth and nonmisleading claims. However, how can claims be truthful and non-misleading without a solid basis of information derived from well-designed scientific research? If dietary supplements can have claims to improve health, or in the case of pregnant women, to alleviate nausea, certainly the public needs to know the basis for those claims. Accurate information in labeling about the basis of a product's claim is needed, both for what the claim is based on

as well as what the claim is not based on. Consumers need to know if there have or have not been well-designed animal studies or randomized clinical trials in human subjects. Consumer education is important.

I would like to focus mainly on the first question:
What are the potential hazards associated with the use of dietary supplements for conditions associated with pregnancy both to the pregnant woman and to the fetus? Should these hazards be considered to be different than hazards to other potential users of dietary supplements?

DIETARY SUPPLEMENTS

First a few words about dietary supplements, these are NOT compounds consisting of one ingredient that has been tested in animals and humans to demonstrate its safety and efficacy. In dietary supplements, there may be potential hazards since

- **The active ingredient is not known,**
- **The other ingredients are not known,**
- **These products may be contaminated with heavy metals such as arsenic, microbes, pesticides, radioactive compounds. We know that there were calcium tablets contaminated with high concentrations of lead.**
- **The concentrations or doses of these products are not known.**
- **The concentration and even the ingredients can vary from batch to batch. Good Manufacturing Practices are strictly optional.**

PREGNANT WOMEN

Shifting now to pregnancy, there are several concerns:

- **When a product is used by a pregnant woman, two individuals are affected – the mother and the unborn fetus. One person is willingly taking a compound and the fetus is unwillingly exposed.**

- **There are striking physiologic differences between the pregnant and non pregnant women, such as in levels of drug binding proteins in the plasma, in amount of fluid retained in the tissues, in cardiac and pulmonary function, and in kidney and liver function both of which help clear drugs and dietary supplements, to name just a few differences.**

- **Others have discussed that a pregnant women may take a dietary supplement for a symptom such as swelling which may indicate a more serious condition needing medical treatment.**

- **Pregnant women may discontinue prescription medications for which scientific information exists and go on a dietary supplement for which we may have little if any scientific information. There is a false sense of security that because dietary supplements may be natural, they are safe. However, we know that there are poisonous plants (such as oleander). And there has been experience with dietary supplements and serious medical problems, such as Eosinophilia Myalgia Syndrome (EMS) and tryptophan.**

- **There could be the possibility of a specific interaction between a dietary supplement and a drug. For example, the same enzymes could metabolize both, and one or both could build up to toxic concentrations and could affect the mother, fetus or both the mother and fetus. We do not know how dietary supplements interact with foods.**

- **Additionally, physiologic concentration of a compound in the body may well be harmless but not harmless when the concentration is increased by taking a dietary supplement. This is particularly a concern for a pregnant women and the fetus.**

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Last but certainly not least, there is always a concern about exposing the fetus to an unknown, untested and potentially dangerous compound. And there are many possibilities for harm to the fetus beyond major structural abnormalities and carcinogenic potential such as affects on the nervous system, the immune system, enzyme systems, on blood forming cells, and many others, all of which are much more difficult to detect.

In thinking about what may affect a developing fetus, timing of exposure is critical. For example, a dietary supplements for nausea of pregnancy are used in the first trimester of pregnancy. This coincides is the critical period of organ development for many systems in the fetus and a dangerous period for teratogenesis. Therefore, dietary supplements marketed for nausea have the potential to adverse affect major organ development in the fetus.

I want to conclude with two suggestions.

First, labeling. Dietary supplements should not be recommended/marketed to pregnant or nursing women until their safety and efficacy for both the mother and fetus has been demonstrated. Norman Farnsworth, PhD, head of the botanical center at the University of Illinois, told me that the World Health Organization (WHO) has issued a series of monographs on dietary supplements and each one has a statement that it

"Should not be used in pregnant and nursing women and in children under 15."

This warning exists because there is so much that is unknown. There is a need for labeling to warn pregnant and nursing women against taking dietary supplements. And there is a need for FDA to be able to regulate them.

Secondly, there needs to be much, much more scientific research to answer the questions on effectiveness, but particularly on safety. There are so many unknowns and so many people are taking these products. We met with the director of the Center for Complementary and Alternative Medicine at Columbia Hospital for Physicians and Surgeons in NY. She said they gave a survey to the patients in the

emergency room with the purpose of ascertaining what kinds of dietary supplements this group of patients was using. The response to the survey on the question, "What dietary supplements are you using?" was a unanimous "no response/none." When a subsample of the group that responded to this survey was interviewed, those interviewed acknowledged that they were taking products and a wide range of products that we call dietary supplements.

- **In research, NIH is playing a role in promoting research in this area and has already established an Office of Dietary Supplements. The NIH Office of Research on Women's Health has as one of its research priorities - building an evidence base for dietary supplements. But their resources are extremely limited and there are so many products that need to be studied. This is a huge area and the government and taxpayer cannot support all the work, and industry would not be happy with the results. If only NIH supported research on dietary supplements, which product would be picked to study, which manufactured product would be studied? If only one manufactured product were studied, could only that manufacturer make claims? Would this put the other manufacturers and consumers at a disadvantage? This would have tremendous implications for the marketplace.**
- **There needs to be collaboration between NIH and FDA and CDC to make sure the right questions are accurately addressed in research.**
- **Industry needs to join with government in performing and supporting research on dietary supplements.**
- **And yes, I think there should be requirements for animal studies and human safety information. Rigorous scientific research is needed. Information on the type of studies, the resultant data, or the lack of it, should be in the labels. A lack of evidence does not mean that these products are safe and effective Anecdotal evidence even over years of use is not the same as solid scientific data.**

FDA's history has been shaped by public health crisis and human tragedies that occurred in vulnerable populations – women and children. Congressional responses to these events have given stronger regulatory laws to protect the public health. We are here to today to try to avoid another human tragedy from happening again.

Thank you.